SUBJECT: Detection of Blood (hemoglobin) residue inside the biopsy channel of an endoendoscope

DEPARTMENT: Central Service/ Endoscopy

APPROVED BY:

EFFECTIVE:

REVISED: 8/2017

PURPOSE: To test for detection of blood (haemoglobin to 0.1µg) residue inside the biopsy channel of a endoscope and to help ensure proper cleaning *and reduce risk to personnel and patients*

POLICY: The EndoCheck™ test detects blood residues inside the various channels of a endoscope. The random testing of endoscope channels such as the biopsy channel is to be used according to the manufacturer's guidelines to ensure that the cleaning process is being performed properly.

RATIONALE:

"***A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected".(9)***

One such problem is blood residual inside the biopsy channel of a endoscope.

Detection of blood residues inside the biopsy channel of a endoscope is very important and distinguishing between blood and other types of residues can be very confusing. Finding any blood residue left inside a biopsy channel that has been cleaned is never good and the implications are even more serious.

There has been a growing concern about the effectiveness of decontamination technique for reusable medical instrumentation in healthcare facilities. Studies have shown the ability of sterilization technologies, which under normal conditions; achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt (7). Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate (8).

- “Current data (Alfa, et al., 2002) indicate that for flexible endoscopes that have been cleaned after use on patients, the average levels of soil markers are as follows: protein, < 6.4 µg/cm2; carbohydrate, < 1.8 µg/cm2; hemoglobin, < 2.2

μg/cm^2; sodium ion, < 1 μmole/cm^2; and endotoxin, < 2.2 EU/cm^2 in the biopsy/suction channel…(ST 79- 10.2 -Section - D.2 Markers)"

Testing any surface that is suspect of blood residue is important. The risk of not only having the biopsy channel cleaned but also any surface properly cleaned is significant especially when handling instruments contaminated with blood of patients infected with hepatitis, CJD, HIV, etc.

The procedures for disinfecting/sterilizing flexible endoscopes are based on years of scientific testing on completely clean instrument surfaces. If endoscopes are not clean, the procedures are ineffective. Dried blood is hazardous to the employees and to the next surgical patient upon which the instruments are to be used. Endoscopes especially the biopsy channel that come in contact with patients need to be free from blood residuals. Looking inside a biopsy channel is nearly impossible without damaging it. The EndoCheck™ does allow you to test specifically for blood residue inside the biopsy channel by swabbing this specific channel surface.

Having a quality system to help monitor the biopsy channel of endoscopes that you might suspect have not been cleaned properly and have blood residue is an important function of any Infection Control program. Testing these channels with the EndoCheck™ and recording results in a log is one such program.

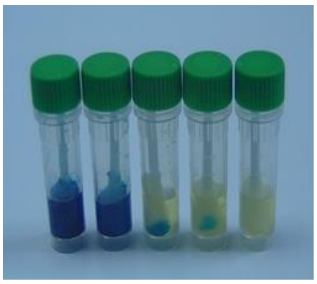
The use of the EndoCheck™ is an excellent tool to use for training of new employees as well as establishing a Quality Improvement Program for checking whether manual or automatic cleaning is done properly. The frequency of testing (i.e. after each cleaning, daily, weekly, etc.) of the endoscopes various channels like the biopsy channels should be done at least weekly. All results should be documented.

PROCEDURE:

EndoCheck™: The test kit for detection of blood residue inside the biopsy channel of an endoscope.

IMPORTANT: This testing must be done after cleaning and before disinfection/sterilization.

Note: A positive result is proof of remaining blood residue in the tested area only.



1. If the test has been refrigerated, allow it to come to room temperature before using.

2. Open the test kit. Included are: indicator vial (transparent cap), activator vial (green cap), and wire with cotton swab at one end.

3. Testing of the biopsy channel is done after cleaning and before the sterilization/disinfection process.

4. Open the indicator vial (A, transparent cap), place the vial into the Holder provided, and transfer the liquid into the activator vial (B, green cap).

5. Moisten the cotton swab with a drop of clean water. Do not use chlorinated water.

6. Insert the swab end of the wire into the endoscope/biopsy channel. Push it all the way through one (1) time.

7. Cut the swab end off, the wire with scissors directly into the vial. Do not touch the swab.

8. Recap the activator vial and shake at least five times.

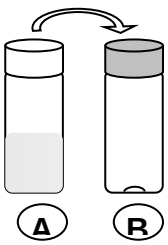
9. To remove the remaining segment of the EndoCheck™ pull the wire out from the distal tip. Dispose in trash according to facility policy.

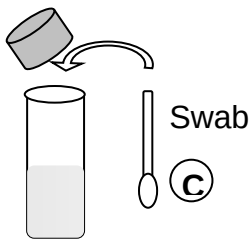
10. Check the swab over a period of 30 seconds for a color change to blue-green, which will indicate blood residues in the tested endoscope. In the presence of large amount of blood residue, the entire indicator solution will become dark blue.

11. Record the result immediately—late color changes are not valid. The yellow color change after activation is a normal reaction and does not indicate residue.

12. If a positive result (blue-green) report that result immediately and clean the endoscope again according to policy and after cleaning retest the endoscope until you get a negative result. Sterilizing or high level disinfecting an endoscope that is dirty can compromise the sterilization process.

13. Dispose of vial after results are recorded according to hospital policy.





A: Indicator-vial (transparent cap), B: activator-vial (green cap) and C: cotton tip swab.

Please Note the Following:

PRINCIPLE
Due to the high content of Peroxidases in blood an enzymatic reaction is used for detection of blood residues.

MEASURING RANGE
The test kit can detect 0.1 µg of blood by showing a slight blue-green spot. 1 µg of blood in the test will already give a dark blue colour.

INTERFERENCES
Oxidizing agent like chlorine or hypochlorite (present in some disinfecting agents and detergents) will give a color change too. In this case the test cannot be used to detect blood residues

STORAGE
Store EndoCheck™ in closed pouches in a cool place 2°C- 25°C. Keep away from light and heat

RESPONSIBILITY:
The Central Service or GI department manager is responsible for training, assuring initiation, completion and analysis of the monitoring assessment activity for testing of blood residuals on various surfaces.

Sample Competency for Cleaning of Endoscopes

Name: _____

Competency Statement: Complies with policy and procedure for cleaning and testing endoscopes (biopsy channels).

Key
1 = Performs independently and consistently. Ask for assistance in new situations.
2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.
Comments:

Competency Achieved: _____**(Date)**

Evaluator: _____

Learner: _____

Critical Behavior	1	2	3
Review Hospital Policy on cleaning of Endoscopes			
Describes the purpose of cleaning and decontamination of the Endoscope			
Selects and wears the appropriate personal protective equipment			
Gather appropriate supplies to perform test on the Endoscope (EndoCheck™, brushes…)			
Leak test the Endoscope			
Removal of all detachable Parts			
Cleaning (brush and syringing) with approved solution (irrigation of all channels) and surface cleaning. Follow manufacture guidelines for cleaning. Rinse according to manufactures guidelines.			
Dry (Air)			
Check channel with EndoCheck™ after cleaning is done			
If the test has been refrigerated, allow it to come to room temperature before using.			

Open the test kit. Included are: indicator vial (transparent cap), activator vial (green cap), and wire with cotton swab at one end.			
Open the indicator vial (A, transparent cap) and transfer the liquid into the activator vial (B, green cap).			
Moisten the cotton swab with a drop of clean water. Do not use chlorinated water.			
Insert the swab end of the wire into the endoscope/biopsy channel. Push it all the way through one (1) time. (Done post cleaning – pre disinfection / sterilization).			
Then cut the swab end off, the wire with scissors directly into the vial. Do not touch the swab. To remove the remaining segment of the EndoCheck pull the wire out from the distal tip. Dispose in trash according to facility policy.			
Recap the activator vial and shake at least five times.			
Check the swab over a period of 30 seconds for a color change to blue-green, which will indicate blood residues in the tested endoscope. In the presence of large amount of blood residue, the entire indicator solution will become dark blue.			
Record the result immediately—late color changes are not valid. The yellow color change after activation is a normal reaction and does not indicate residue			

Follow Hospital Policy on the Sterilization / disinfection of the endoscope.

Remember to all ways follow manufactures guidelines on cleaning and sterilization of all endoscopes.

EndoCheck™ Test Log

Test Date	Tester Initials	Channel Tested	EndoCheck™ Result	Action Taken	Comments	Endoscope #

Record the Color Change for EndoCheck Result

Check the swab over a period of 30 seconds for a color change to blue-green, which will indicate blood residues in the tested endoscope. In the presence of large amount of blood residue, the entire indicator solution will become dark blue.

REFERENCES:

1. Highlights of **AAMI ST79**:

- AAMI realizes that the efficacy of any high-level disinfection/sterilization process, including saturated steam, depends on a consistent system for lowering and limiting bio-burden before high-level disinfection/sterilization.
- Staff qualifications, training, and continuing education are important: "…. Personnel should receive in-service training for all new instrumentation, devices, and equipment. All orientation, on-the-job, and in-service training should be documented…." (Section 4.3.1)
- Regarding verification of the cleaning process: "…Sterile processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. ***Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function.*** A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically…." (Section 7.7.5)

2. Highlights of **ANSI/AAMI ST91**:2015, "Flexible and semi-rigid endoscope processing in health care facilities"

- "Testing cleaning efficacy: The facility's onsite quality assurance program should include ways to verify that the cleaning equipment used for processing of medical devices is working. Testing the equipment upon installation, during routine use (daily) and on all cycles used, after repairs, and when changing to a new type of cleaning solution allows the user to verify its continued effectiveness... Manufacturer's written IFU should be consulted for recommendations of types and frequency of cleaning efficacy testing. The frequency of testing the efficacy of the manual cleaning step should occur on a regular basis, weekly or preferably daily (Drosnock 2014, Alfa 2014).

- Numerous studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing…

3. Excerpts from published articles:

- *57% of centers that process endoscopes were not in compliance with basic national standards.*[i]

- ***"Our findings underline the potential for blood fixation, not only by glutaraldehyde, but also by peracetic acid, and support the evidence that effective cleaning should precede the chemical disinfection."***[ii]

- 53% of biopsy ports valves exhibited some form of debris or potential contamination after cleaning.[iii]

- *"Company blames bronchoendoscope infections on poor cleaning."*[iv]

- Endoscopes have been implicated in the transmission of disease (specifically nosocomial infections) when appropriate cleaning, disinfection or sterilization procedures were not employed. Of particular significance is the need to **thoroughly manually clean equipment prior to** any manual or automated disinfection or sterilization process.[v]

- "It is very clear that every documented case of patient infection linked to a contaminated endoscope is because of a breach of some of the reprocessing protocol. If you look back on the history, that is what it is – improper disinfection; you don't dry the endoscope; inadequate cleaning; or somebody forgot to clean the biopsy channel. It has been more human error than anything else… Rules No.1, 2 and 3 are to educate the people who are cleaning the endoscopes--how and what should be done. If I had it my way, I would have them take a test before letting them do the cleaning."[vi]

- In one case two colonoscopy patients were infected with hepatitis C (HCV) from an endoscope contaminated by an earlier patient. The investigation concluded that the biopsy channel had not been properly cleaned and the disinfection failed. Only two hours had elapsed between the first patient and the last, so even if samples had been taken immediately after the first patient, traditional microbiology results would not have been available in time to prevent cross-infection. [vii]

4. Technical sources
EndoChek™ information
http://www.healthmark.info/proformance.html
5. Blood as a Soil on Surgical Instruments ; Cleaning Profile, Cleaning , Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385
6. Standardized Test Soil Blood 1 : Composition, Preparation, Application ; M.Pfeifer, Zentr Steril 1998;6 (6);304-310
7. *Alfa,M.,et al, Comparison of Ion Plasma, Vaporized Hydrogen Peroxide, and 100% Ethylene oxide Sterilization to the 12/88 Ethylene oxide gas Sterilizer, Infection Control and Hospital epidemiology, 1996; 17:92-100*
8. AORR Journal; July 1995,Vol62, NO1;DesCoteaux, Poulin, Julien, Guidoin

9. ANSI/AAMI-ST 79;2006
10. http://www.proformance-test.com

11. AORN GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES 2016:

a. **Manual cleaning of flexible endoscopes should be verified using cleaning verification** tests when new endoscopes are purchased and at established intervals **(eg, after each use, daily).**

i. Cleaning verification tests are used to verify the ability of the cleaning process to remove, or reduce to an acceptable level, the organic soil and microbial contamination that occurs during use of a reusable device. Cleaning verification tests include chemical reagent tests for detecting clinically relevant soils (eg, protein, carbohydrate) and ATP. **Periodic verification of cleaning effectiveness may help reduce errors in manual cleaning and improve effectiveness**

ii. Auditing the manual cleaning of flexible endoscopes provides an objective method for verifying cleanliness and helps ensure that insufficiently cleaned flexible endoscopes are recleaned before HLD or sterilization.

iii. There are a number of tests that can be used to assess cleaning efficacy. Chemical tests involve the use of a reagent and observing for a color change that indicates the presence of organic markers such as protein or blood. In a dual phase (ie, simulated-use, inuse) study to validate the use of an audit tool composed of reagent test strips in 43 endoscopy clinics across Canada, Alfa et al collected samples from 30 patient-used endoscopes (ie, 10 colonoscopes, 10 duodenoscopes, 10 gastroscopes) and tested them for residual protein, carbohydrate, and hemoglobin using the audit tool test strips. The test strips had three reagent pads designed to rapidly detect organic residuals of protein, carbohydrate, and hemoglobin after manual cleaning. The researchers confirmed that the audit tool flagged endoscopes with residual protein, hemoglobin, or carbohydrate.

v. There are quantitative tests that can be used for cleaning verification testing of other residual soils, including:

- protein,
- carbohydrate,
- hemoglobin,

vi. The multidisciplinary team should evaluate the need to implement protocols for cleaning verification testing of flexible duodenoscopes with elevator channels.

b. Records related to flexible endoscope processing should include the date and time, identity of the endoscope and endoscope accessories, method and **verification of cleaning** and **results of cleaning verification testing**.

12. SGNA Standard of Infection Prevention in the Gastroenterology Setting:

a. The use of cleaning monitors for automated washers may help to ensure adequate functioning (Alfa, 2013).

b. "Visibly clean" is a method routinely used to assess the adequacy of manual cleaning (Alfa et al., 2012; Rutala et al., 2008). This may involve the use of a magnifying glass to inspect for gross soil. Visual inspection is insufficient to determine cleaning adequacy in narrow and internal channels of a scope and cannot detect microorganisms or bioburden (Alfa, 2014). **Rapid cleaning monitors are available. These monitors can provide documentation on cleaning efficacy** but do not reflect microbial activity. **Real-time testing of endoscope lumens/elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD.** Facilities should consider the use of monitors to verify ongoing cleaning adequacy (Alfa, 2013).

c. Once there is confirmation that an endoscope has been properly reprocessed, it is suggested that a system exist for identifying scopes that are clean and ready to use (Rutala & Weber, 2004; CDC, 2015)

13. SGNA Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes:

a. **Note:** It is impossible to visualize internal channels. Literature suggests that, to confirm the **adequacy of manual cleaning, a rapid cleaning monitor** (or rapid audit tool) for residual organic soil can be used prior to high-level disinfection (Visrodia et al., 2014). If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. The frequency of the testing should be determined by the individual institutions (Alfa et al., 2013, 2014; AAMI, 2015; ASGE, 2014).

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[i] Infection Control and Hospital Epidemiology ; Volume 23 ; 2002

[ii] Kampf G,Bloss,Martiny H;Surface fixation of dried blood by glutaraldehyde and peracetic acid;JHI; June 2004; 57(2): 139-143

[iii] Endonurse 12/6

[iv] 3/7/02; http://www.hpnonline.com/dailyupdates/march_02.html

[v] http://www.gov.mb.ca/health/publichealth/cdc/fs/endoscopy.pdf, page 1

[vi] page 16; New Technologies Require thorough reprocessing; EndoNurse; August/September 2005

[vii] *The New England Journal of Medicine* **337**, 237-240 (1997).